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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,367	12/22/2003	Mahendra R. Patel	4-33515P1	7967
1095 7590 03/29/2007 NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER KENNEDY, SHARON E	
			ART UNIT	PAPER NUMBER
			1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/743,367	Applicant(s) PATEL ET AL.	
	Examiner Sharon E. Kennedy	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/03/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al., US 2005/0064034. The Li applicant claims priority to a provisional application having an earlier filing date. Li discloses the use of two polymers having different viscosities V1 and V2. See [0060]. Li also states that the polymer V1 having a viscosity less than 50 cps may be present in an amount of more than 50% by weight. See [0062]. The preferred drugs are set forth in [0049]-[0050]. The preferred low viscosity polymer V1 is hydroxypropylmethylcellulose. See [0063]. See also Tables 6 and 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussain et al., US 7,037,523. Hussain discloses a controlled release composition for antibiotic drugs such as clarithromycin (column 5, line 33) in an amount from 30 to 75 wt. % (column 5, line 34) in combination with insoluble polymers such as ethyl cellulose having a viscosity grade of 20 cps (column 5, lines 39-56). The insoluble polymers are present in an amount from 10 to about 40 weight percent (column 5, line 60). Hussain fails to disclose a polymer component being present in an amount greater than 50 weight percent. However, the examiner takes the position that in view the ranges are close (the Hussain 40 wt % as opposed to the claimed greater than 50 wt %), it would be obvious to one of ordinary skill in the art to slightly modify the ingredients of the Hussain to include more than 50 wt % of polymer dependent upon the drug used, its activity level, and the patient need. Regarding claim 2, Hussain prefers ethyl cellulose (column 5, lines 39-47), however, it would be *prima facie* obvious to one of ordinary skill in the art to choose methyl cellulose in view of the close structural similarity in the lack of a showing of criticality. See MPEP 2144.09 for the case law concerning *prima facie* obviousness rejections using this rationale. Regarding claim 6,

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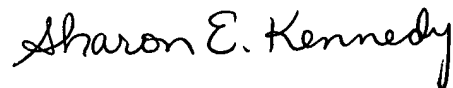
see column 5, line 13, disclosure of clarithromycin. See column 5, lines 33-38 for the drug weight percentage ranges.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussain as applied to claims 1-2 above, and further in view of Al-Razzak et al., US 6,010,718. Al Razzak exemplifies that the use of low viscosity hydroxypropylmethyl cellulose (Methocel), etc., is well known in the art for providing sustained release tablet formulations for antibiotics such as clarithromycin (Table 1). It would be obvious to one of ordinary skill in the art to substitute the ethyl cellulose for the Methocel in view that the identical antibiotics are delivered, indicating a high probability of success.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.



Sharon E. Kennedy
Primary Examiner
Art Unit 1615